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1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

4 IN RE: NEW ENGLAND : MDL No. 2419

5 COMPOUNDING PHARMACY, INC. : Docket No.:

6 PRODUCTS LIABILITY LITIGATION: 1:13-md-2419(RWZ)

7 -----:

8 This document relates to: :

9 :
10 ARNETTA, ET AL v. BOX HILL :

11 SURGERY CENTER, LLC, ET AL : DEPOSITION OF
DAVID MAINE, M.D.

12 No. 1:14-cv-14022-RWZ :

13 :
14 BOWMAN, ET AL v. BOX HILL :

15 SURGERY CENTER, LLC, ET AL :

16 No. 1:14-cv-14028-RWZ :

17 :
18 DAVIS, ET AL v. BOX HILL :

19 SURGERY CENTER, LLC, ET AL :

20 No. 1:14-cv-14033-RWZ :

21 :
22

	Page 2	Page 4
1 DREISCH, ET AL v. BOX HILL :		1 APPEARANCES:
2 SURGERY CENTER, LLC, ET AL :		2 ON BEHALF OF PLAINTIFFS ARNETTA, BOWMAN,
3 No. 1:14-cv-14029-RWZ :		3 DAVIS, DREISCH, FARTHING, KASHI, TORBECK
4 :		4 AND HANDY:
5 FARTHING, ET AL v. BOX HILL :		5 Law Offices of Peter G. Angelos, P.C.
6 SURGERY CENTER, LLC, ET AL :		6 JAY D. MILLER, ESQUIRE.
7 No. 1:14-cv-14036-RWZ :		7 jmiller@lawpga.com.
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10 SURGERY CENTER, LLC, ET AL :		10 100 North Charles Street.
11 No. 1:14-cv-14026-RWZ :		11 Baltimore, Maryland 21201.
12 :		12 (410) 649-2000
13 TORBECK, ET AL v. BOX HILL :		13
14 SURGERY CENTER, LLC, ET AL :		14 ON BEHALF OF PLAINTIFF ROZEK:
15 No. 1:14-cv-14023-RWZ :		15 Cohen, Placitella & Roth, P.C.
16 :		16 MCHALEN COREN, ESQUIRE.
17 HANDY, ET AL v. BOX HILL :		17 mcoren@cprlaw.com.
18 SURGERY CENTER, LLC, ET AL :		18 2001 Market Street.
19 No. 1:14-cv-14019-RWZ :		19 Suite 2900.
20 -----		20 Philadelphia, Pennsylvania 19103.
21		21 (215) 567-3500
	Page 3	Page 5
1 Deposition of DAVID MAINE, M.D., was		1 APPEARANCES CONTINUED:
2 taken on Wednesday, March 8, 2017, commencing at		2 ON BEHALF OF THE DEFENDANTS:
3 4:36 p.m., at Mercy Medical Center, 435 St. Paul		3 Pessin Katz Law, P.A.
4 Place, 4th Floor, Baltimore, Maryland, before		4 GREGORY K. KIRBY, ESQUIRE.
5 MICHELE D. LAMBIE, Notary Public.		5 gkirby@plaw.com.
6 -----		6 901 Dulaney Valley Road.
7		7 Suite 400.
8		8 Towson, Maryland 21204.
9		9 (410) 938-8800
10		10
11 ALSO PRESENT; Ashley E. Geno, Esquire		11
12 (via telephone)		12
13 Reported By:		13
14 Michele D. Lambie, CSR-RPR		14
15		15
16		16
17		17
18		18
19		19
20		20
21		21

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1	EXAMINATION INDEX			
2	DAVID MAINE, M.D.		1 highlights, if I could.	
3	BY MR. MILLER	7	2 MR. KIRBY: Can you hold on for one	
	BY MR. COREN	173	3 second?	
4	R BY MR. MILLER	274	4 MR. MILLER: Sure.	
	BY MR. KIRBY	276	5 (Whereupon, Ms. Houston enters the	
5	R BY MR. MILLER	282	6 deposition room.)	
6			7 (Recess taken -- 4:37 p.m.)	
7	EXHIBIT INDEX		8 (After recess -- 4:38 p.m.)	
8	MARKED		9 BY MR. MILLER:	
	DAVID MAINE, M.D.		10 Q. Just a couple highlights, Doctor. You	
9	1626-1 Standards of Professionalism: Expert Witness Guidelines	24	11 finished your residency in '07; is that correct, I	
10	1626-2 Report	24	12 mean a fellowship?	
11	1626-3 Prescription Order Form	178	13 A. Yes, I believe that's correct.	
12	1626-4 Transmission Verification Report with attachments	183	14 Q. Then in that same year, you became	
13	1626-5 Commonwealth of Massachusetts Board Of registration in Medicine Prescribing Practices, Policies and Guidelines	196	15 director; is that correct, of the --	
14	1626-6 Massachusetts Statutes for Chapter 94	209	16 A. That's correct.	
15	1626-7 2012 Version of Maryland Health Occupations	226	17 Q. Medical director?	
16	1626-8 Article	259	18 A. That's correct. Yes.	
17			19 Q. How do you finish your fellowship and	
18			20 become the head honcho the same day?	
19			21 A. So this health system did not have a pain	
20				
21				
	PROCEEDINGS	Page 7		Page 9
1	DAVID MAINE, M.D.,		1 center at all or any division of that sort, and so	
2	the Deponent, called for examination by the		2 I started it with the support, obviously, of the	
3	Plaintiffs, being first duly sworn to tell the		3 institution.	
4	truth, the whole truth, and nothing but the truth,		4 Q. Now, were you a fellow under Dr. Cohen?	
5	testified as follows:		5 A. I was.	
6	EXAMINATION		6 Q. Are you aware that he's also designated	
7	BY MR. MILLER:		7 as an expert in this case?	
8	Q. Full name and address for the record.		8 A. I am.	
9	A. David Maine. Work address, I assume?		9 Q. Have you had a chance to review any of	
10	11 345 St. Paul Place, Baltimore, Maryland 21202.		10 his testimony?	
11	12 Q. Dr. Maine, as you know, my name is Jay		11 A. I read through about, I think, the first	
12	13 Miller with the Law Offices of Peter Angelos, and		12 40 to 49 pages yesterday, and then I zonked out.	
13	14 we're here today to take your deposition on issues		13 You guys talked for a while.	
14	15 relating to a number of cases.		14 Q. The same thing happened to Mike.	
15	I've been provided with your CV and a		15 MR. COREN: Yeah. It's a page turner,	
16	17 copy of your report. I'd like to go through that.		16 right?	
17	18 You've had your deposition taken before?		17 MR. KIRBY: Keep reading the same page	
18	19 A. Yes.		18 over and over.	
19	20 Q. You were kind enough to give us a list of		19 BY MR. MILLER:	
20	21 cases you have been involved with, so just a couple		20 Q. So you read some of it?	
			21 A. Yes.	

<p style="text-align: right;">Page 22</p> <p>1 context, but it seems like a reasonable statement; 2 yes.</p> <p>3 Q. Would you agree because of your unbiased 4 nature if you read something or you learn something 5 throughout this case, throughout this deposition or 6 whenever, if it's contrary to the position that you 7 have already indicated, because you're unbiased and 8 you want to comply with the guidelines, you will 9 tell the attorney and indicate that, Hey, my 10 opinion is not what I thought it was?</p> <p>11 A. Sure. I mean, I think, you know, when I, 12 when I take a case, it's fairly clear with counsel 13 that my, my opinion is obviously always subject to 14 change if there's new information provided to me in 15 respect to a case, particularly as it pertains to 16 injuries where sometimes I don't get all of the 17 information at the time of my clinical exam or so 18 on and so forth, so.</p> <p>19 Q. Now, you understand that I have not had a 20 chance to talk to you about this case before. So 21 we have been provided what you have signed as to be</p>	<p style="text-align: right;">Page 24</p> <p>1 MR. MILLER: I'm not asking about the 2 drafting, just his final report.</p> <p>3 BY MR. MILLER:</p> <p>4 Q. This final version, you didn't type any 5 of this?</p> <p>6 A. If I had to type this, I would still be 7 typing right now.</p> <p>8 MR. COREN: Objection. Just so we're 9 clear on the record, could we give it an exhibit 10 number?</p> <p>11 MR. MILLER: Sure.</p> <p>12 (Whereupon, Maine Deposition Exhibit 13 Number 1626-1, Standards of Professionalism: Expert 14 Witness Guidelines, marked for identification.)</p> <p>15 (Whereupon, Maine Deposition Exhibit 16 Number 1626-2, Report, marked for identification.)</p> <p>17 BY MR. MILLER:</p> <p>18 Q. You can use yours. I just want to sit 19 this here.</p> <p>20 A. That's fine.</p> <p>21 Q. So the 23 pages was arrived at to a</p>
<p style="text-align: right;">Page 23</p> <p>1 your report in this case. I believe your signature 2 appears on page 23?</p> <p>3 A. Correct.</p> <p>4 Q. It shows me you signed it in October of 5 2016?</p> <p>6 A. Um-hum.</p> <p>7 Q. And you -- how did you prepare this 8 report?</p> <p>9 A. So I first reviewed two giant boxes of 10 information that made my head want to blow up, and 11 then I spent some time synthesizing it. And then I 12 had numerous telephone conversations with 13 Mr. Kirby, and I think it was solely Mr. Kirby, 14 where he asked me questions, and I articulated my 15 opinion. We would -- he would -- that's 16 essentially how I did it.</p> <p>17 Q. Did you type the pages?</p> <p>18 A. No.</p> <p>19 MR. KIRBY: I'm just going to object 20 based on protected information of drafting in the 21 process which I consider privileged.</p>	<p style="text-align: right;">Page 25</p> <p>1 series of questions and answers with Mr. Kirby, and 2 then ultimately after a number of conversations 3 just with Mr. Kirby, you telling him information, 4 he put together a typed 23-page report. You 5 received this, and I take it you reviewed it before 6 you signed it?</p> <p>7 A. Of course, yes. I, I made some changes 8 here and there, but that's correct.</p> <p>9 Q. And then so this 23-page report contains 10 the entirety of your opinions in this case?</p> <p>11 A. It's a good summary.</p> <p>12 Q. Do you have any changes you want to make 13 before we move on?</p> <p>14 MR. KIRBY: Objection to form and the 15 broad nature of the question. You can answer.</p> <p>16 THE WITNESS: Not specifically.</p> <p>17 BY MR. MILLER:</p> <p>18 Q. Have you reviewed any of the reports that 19 Dr. Cohen filed in this case?</p> <p>20 A. No.</p> <p>21 Q. How about the report of Dr. Larkin?</p>

Page 26	Page 28
1 A. No.	1 Q. -- and to help with administrative
2 Q. Have you seen the report of	2 functions, such as addressing inventory and
3 Dr. Manchikanti?	3 ensuring that medications and other supplies are
4 A. No. I read his deposition.	4 fully stocked. Where did you get that information?
5 Q. Have you read your report prior to today?	5 A. I don't recall specifically.
6 A. I read it, I think, in September of 2016	6 Q. Do you have some specific recollection of
7 and maybe in August of 2016 when it was being	7 reading something that led you to the conclusion
8 prepared.	8 that Mr. Vickers helps with addressing inventory
9 Q. Is it fair to say at the time you read	9 and ensuring that stock is kept up to date?
10 it, when you signed it, you were confident that	10 A. It might, it might have been
11 your opinions were truthful, unbiased and	11 Dr. Bhamhani's deposition. I just don't recall
12 scientifically sound?	12 specifically.
13 A. These are my opinions.	13 Q. All right. The next paragraph,
14 Q. Well, they're obviously truthful?	14 Dr. Maine, under B, Medication Purchasing, the
15 A. So they're truthful, yes.	15 fourth line down, it says, She -- you're referring
16 Q. And unbiased?	16 to Dr. Bhamhani -- continued to use it -- and
17 A. Yes, they're my opinions. These are my	17 we're talking about MPA, correct?
18 opinions.	18 A. Correct.
19 Q. Okay. No other doctor's? They're yours?	19 Q. Continued to use it out of a concern for
20 A. No. I mean, they're only biased by my	20 potential adverse events due to preservatives. I
21 experience in clinical practice.	21 want to stop right there.
Page 27	Page 29
1 Q. You wouldn't copy anybody else's opinion.	1 A. Sure.
2 These are your own personal opinions that you	2 Q. What specific facts did you rely on to
3 reached, right?	3 conclude that Dr. Bhamhani used MPA because she
4 MR. KIRBY: Object to the form.	4 was concerned about adverse events due to
5 THE WITNESS: Yeah. These are, these are	5 preservatives?
6 my opinions. Now, it's not to say that others	6 A. Well, Dr. Bhamhani's deposition spoke to
7 cannot have the same opinions, but they're my	7 that, so that was the primary part of the medical
8 opinions.	8 record that I used to garner that, that opinion.
9 BY MR. MILLER:	9 I think she spoke to specifically that
10 Q. If you could turn to page 3, at the top	10 she had worked with another provider who had used
11 you say that these opinions contained herein are	11 NECC. I think she might have been
12 generally relied on your education, training,	12 working -- she has worked for several years using
13 experience and then the materials you reviewed,	13 it uneventfully.
14 correct?	14 She had some negative experiences with
15 A. Correct.	15 other steroids, and I think it was shaping those
16 Q. Down at the bottom of page 3 where your	16 experiences, both positive and negative, that
17 report states that, Box Hill Surgery Center has a	17 ultimately resulted in her reason of using the
18 nurse administrator, Andrew Vickers, and you say,	18 preservative-free MPA, that she had a very positive
19 Mr. Vickers works part time with Dr. Bhamhani to	19 experience with.
20 assist her when performing pain injections --	20 Q. So it's your belief that Dr. Bhamhani
21 A. Um-hum.	21 specifically used preservative free or the MPA

<p style="text-align: right;">Page 46</p> <p>1 A. I mean, I think that's reasonable. She 2 used it thousands of times, had no problems and 3 decided to use it. Just like I used, what I have 4 used at Hopkins, I decided to use it. It's kind of 5 the same logic.</p> <p>6 Q. Her prior boss used it, so she's going to 7 use it?</p> <p>8 MR. KIRBY: Objection to form.</p> <p>9 THE WITNESS: I think, I think we're 10 saying the same thing.</p> <p>11 BY MR. MILLER:</p> <p>12 Q. Right.</p> <p>13 A. She had a good experience. She used it 14 at her prior employer, and she decided to use it in 15 her solo practice.</p> <p>16 Q. And despite the way this is worded, I 17 mean, really isn't that the extent of her basis for 18 using it --</p> <p>19 MR. KIRBY: Objection to form.</p> <p>20 BY MR. MILLER:</p> <p>21 Q. -- the lack of any prior problems?</p>	<p style="text-align: right;">Page 48</p> <p>1 appearing on the schedule or sometimes the schedule 2 itself. NECC led Box Hill to believe that doing it 3 that way would comply with NECC's requirements.</p> <p>4 Do you believe that at the time</p> <p>5 Dr. Bhamhani was doing this in 2012 that that way 6 of ordering prescription medication from a 7 compounding lab complied with Massachusetts's law 8 in NECC's country and Maryland law?</p> <p>9 MR. KIRBY: Objection to form and 10 foundation.</p> <p>11 BY MR. MILLER:</p> <p>12 Q. Sending a schedule just showing patient 13 name and ordering medication?</p> <p>14 MR. KIRBY: Objection to form. He's not 15 going to be a regulatory expert. Go ahead.</p> <p>16 THE WITNESS: So I'll say this: I mean, 17 I can't speak to the Massachusetts's law. I can 18 tell you that it was certainly standard practice at 19 the time.</p> <p>20 BY MR. MILLER:</p> <p>21 Q. You now know that that's not, it wasn't</p>
<p style="text-align: right;">Page 47</p> <p>1 A. When you say it like that, it means that 2 it -- it comes off as you're saying that that is 3 not a very reasonable reason.</p> <p>4 Q. But that's my job. You can still agree 5 with it.</p> <p>6 A. I understand, but, actually, I think that 7 is a, that is perfectly sufficient and reasonable 8 to make a decision.</p> <p>9 Patients have a good therapeutic effect, 10 you have a good experience, no negative effects. 11 Negative effects shape what we do, just like this 12 is shaping what we do, so I -- yes.</p> <p>13 Q. Okay. Fair enough. Let's go down a 14 quarter of the way on that page, and then it says, 15 NECC was Box Hill's sole supplier of MPA prior to 16 the issues at hand.</p> <p>17 And then you say, At some point in 2012, 18 Box Hill was informed by NECC that NECC needed a 19 list of patient names from Box Hill for patients 20 who had or would be receiving a steroid injection. 21 Dr. Bhamhani complied by sending a list of names</p>	<p style="text-align: right;">Page 49</p> <p>1 appropriate, don't you?</p> <p>2 MR. KIRBY: Objection to form.</p> <p>3 THE WITNESS: Well, I mean, I would say 4 certainly now that it is not appropriate, but at 5 the time, it was absolutely standard practice. 6 And, you know, I'm -- whether it's appropriate or 7 not is a different question, but --</p> <p>8 BY MR. MILLER:</p> <p>9 Q. I didn't mean to cut you off by sighing 10 like that, so you go ahead if you want to finish.</p> <p>11 A. -- but at the time, that was standard 12 practice in terms of ordering medications.</p> <p>13 Q. When you say standard practice, are you 14 referring to doctors that you work with?</p> <p>15 A. Well, like I said, I am a partner in a 16 surgery center, and we use a compounding pharmacy 17 there. Some providers prefer MPA. It's used for 18 eye cases. I think it's used for some other 19 peripheral cases that I'm not involved in, and that 20 was common, commonplace to order it that way.</p> <p>21 You could order three, four, five vials</p>

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<p>1 under a single patient's name. You would get the 2 vials, and then when you administered the 3 medication, even though that medication may have 4 been going to a different patient, you would write 5 the lot number and record it, obviously, for that 6 patient. But in terms of ordering, this is what 7 the pharmacies expressed was necessary, and it was 8 done that way, so I considered it standard 9 practice.</p> <p>10 Q. Since the NECC meningitis outbreak, is it 11 fair to say you've learned that that was, it may 12 have been standard practice, but it certainly did 13 not comply with the law?</p> <p>14 MR. KIRBY: Objection to form. Again, 15 he's not a regulatory expert.</p> <p>16 BY MR. MILLER:</p> <p>17 Q. You can answer.</p> <p>18 A. I mean, I think our knowledge and 19 understanding of these issues has certainly come to 20 the forefront after the NECC outbreak, so I think 21 our understanding of that is much clearer, and, and</p>	<p>1 Q. So your opinion that she complied with 2 the standard of care in 2012 by ordering it the way 3 she did by using the schedule is based on your 4 belief that the standard of care was what everybody 5 was doing --</p> <p>6 A. Well --</p> <p>7 Q. -- regardless of what the law said?</p> <p>8 MR. KIRBY: Objection to form and 9 foundation.</p> <p>10 THE WITNESS: Well, I mean, when 11 I -- when I say the word standard practice, 12 standard practice or standard of care, I'm thinking 13 what any reasonably appropriate physician would do 14 in the same situation --</p> <p>15 BY MR. MILLER:</p> <p>16 Q. Understood.</p> <p>17 A. -- and that's what was being done. I 18 remember talking about it at conferences. Everyone 19 was starting up their practices. People were 20 talking about where they were ordering medications 21 and how they were doing it, so this was</p>
<p>1 I will say that.</p> <p>2 Q. What's your understanding now of what the 3 law requires when ordering a prescription --</p> <p>4 MR. KIRBY: Objection to form.</p> <p>5 BY MR. MILLER:</p> <p>6 Q. -- from a compounding pharmacy?</p> <p>7 A. I think you need -- I think you need a 8 prescription or a specific prescription for a 9 patient for a specific quantity for that patient.</p> <p>10 The details in terms of ordering and certifications 11 I can't speak to.</p> <p>12 Q. And you learned that that's not a new 13 law. That was in existence in 2012?</p> <p>14 MR. KIRBY: Objection to form.</p> <p>15 THE WITNESS: Again, I wasn't familiar 16 with the law in 2012 --</p> <p>17 BY MR. MILLER:</p> <p>18 Q. I understand.</p> <p>19 A. -- or 2010. I'm, I'm really marginally 20 familiar with it now, other than there seems to be 21 quite a bit more regulatory oversight.</p>	<p>1 commonplace.</p> <p>2 You know, I mean, I, I can't speak to 3 what the pharmacy regulations were. I mean, that's 4 on pharmacies, but, you know, for physicians, that 5 was commonplace, and I, I would call standard 6 practice.</p> <p>7 Q. I'll ask you to turn to page 5 for me.</p> <p>8 When you make a statement at the top like this 9 where it says, Each of the patients in the instant 10 actions treated by Bhambhani presented, in most 11 cases, as a referral from another physician, what's 12 your source of that? Where do you get that 13 information?</p> <p>14 A. I don't recall specifically, but 15 Dr. Bhambhani implied in her deposition that she 16 used these medications for treating patients with 17 back, neck pain, so on and so forth, so.</p> <p>18 Q. Do you think it's fair for me to make the 19 assumption that a statement like that where you 20 really don't recall the source is likely a 21 statement made by the attorney in the report, that</p>
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